OIPE IAP59
FEB 21 2006
PATENT & TRADEMARK OFFICE

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application No.	09/802,425
Filing Date	March 9, 2001
First Named Inventor	Dean Rhoades
Art Unit	1616
Examiner Name	Frank I. Choi
Total Number of Pages in This Submission	88
Attorney Docket Number	5309P001X

ENCLOSURES ***(check all that apply)***

- ☒ Fee Transmittal Form
 - ☐ Fee Attached
- ☐ Amendment / Response
 - ☐ After Final
 - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
 - ☐ PTO/SB/08
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
 - ☐ Basic Filing Fee
 - ☐ Declaration/POA
- ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
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- ☐ Request for Refund
- ☐ CD, Number of CD(s)
 - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
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- ☒ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below):*

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Remarks

RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF (2 PGS.)
AMENDED REPLACEMENT APPEAL BRIEF (83 PGS)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	William Thomas Babbitt, Reg. No. 39,591 BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP
Signature	William T Babbitt
Date	February 17, 2006

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Signature		Date	**February 17, 2006**

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FEE TRANSMITTAL for FY 2005

Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27.

TOTAL AMOUNT OF PAYMENT ($)

Complete if Known	
Application Number	09/802,425
Filing Date	March 9, 2001
First Named Inventor	Dean Rhoades
Examiner Name	Frank I. Choi
Art Unit	1616
Attorney Docket No.	5309P001X

METHOD OF PAYMENT *(check all that apply)*

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1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
2053	130	2053	130	Non-English specification	
1251	120	2251	60	Extension for reply within first month	
1252	450	2252	225	Extension for reply within second month	
1253	1,020	2253	510	Extension for reply within third month	
1254	1,590	2254	795	Extension for reply within fourth month	
1255	2,160	2255	1,080	Extension for reply within fifth month	
1401	500	2401	250	Notice of Appeal	
1402	500	2402	250	Filing a brief in support of an appeal	
1403	1,000	2403	500	Request for oral hearing	
1451	1,510	2451	1,510	Petition to institute a public use proceeding	
1460	130	2460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
1809	790	1809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	

Other fee (specify) _____

SUBTOTAL (2) ($)

SUBMITTED BY *Complete (if applicable)*

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Signature				Date	02/17/06

Based on PTO/SB/17 (12-04) as modified by Blakely, Sokoloff, Taylor & Zafman (wlr) 12/15/2004.
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OIPE IAP59
FEB 21 2006
PATENT & TRADEMARK OFFICE

Docket No.: 005309.P001X

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for:	Examiner: Frank I. Choi
Dean L. Rhoades	Art Group: 1616
Serial No.: 09/802,425	
Filed: March 9, 2001	
For: **COMPOSITION, APPARATUS AND METHOD FOR SKIN REJUVENATION**	

RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Non-Compliant Appeal Brief mailed January 19, 2006, Appellant submits an Amended Replacement Appeal Brief. In regard to the Examiner's objection to the "Status of claims" under 37 CFR §41.37(c)(1)(iii), Appellant respectfully submits Appellant stated in the Appeal Brief as originally filed that Claims 1-3, 5, 7 and 21-23 are appealed and indicated in the "Claims appendix" that claims 4 and 8-20 were cancelled. Nevertheless, Appellant has amended the statement of the status of the claims to further recite that Claims 4, 6 and 8-20 are cancelled.

In regard to the Patent Office's objection to the "Claims appendix", Appellant respectfully notes, nowhere within 37 CFR §41.37(c)(1)(viii) is it stated that the claims

appendix must set forth only a copy of the appealed claims not all claims and in fact the Patent Office states only that the appendix "should only set forth a copy of the appealed claims and not all claims" (emphasis added). Thus, Appellant believes the "Claims appendix" as originally submitted was in compliance with 37 CFR §41.37(c)(1)(viii). Nevertheless, Appellant has amended the "Claims appendix" to list only Claims 1-3, 5-7 and 21-23 pursuant to the Patent Office's request.

Appellant has further amended the "Evidence appendix" to provide a statement setting forth where in the record the evidence was entered by the Patent Office pursuant to the Patent Office's request. With respect to evidence not yet entered, Appellant has provided a statement requesting entry of such evidence.

Lastly, Appellant has deleted the heading "Conclusion and relief" in the interest of avoiding further objections to the Appeal Brief.

In view of the above-referenced amendments, Appellant respectfully submits the Amended Replacement Appeal Brief is in compliance with 37 CFR 41.37(c).

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR, & ZAFMAN LLP

Dated: 2/17/06 By: William T Babbitt

William Thomas Babbitt, Reg. No. 39,591

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Jean Svoboda

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FEB 21 2006
PATENT & TRADEMARK OFFICE

PATENT
Attorney's Docket No. 005309.P001X

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for:	Examiner: Frank I. Choi
Dean L. Rhoades	Art Group: 1616
Serial No.: 09/802,425	
Filed: March 9, 2001	
For: **COMPOSITION, APPARATUS AND METHOD FOR SKIN REJUVENATION**	

AMENDED REPLACEMENT APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notification of Non-Compliant Appeal Brief mailed January 19, 2006, Appellants submit the following Amended Replacement Appeal Brief pursuant to 37 C.F.R. § 41.37 for consideration by the Board of Patent Appeals and Interferences. Please charge any additional amount due or credit any overpayment to the Deposit Account 02-2666.

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I. REAL PARTY IN INTEREST

Dean L. Rhoades, the party named in the caption, assigned his rights to the subject application through an Assignment recorded on May 18, 2001 at reel and frame 011814/0345 to Dermanew, Inc., ("Dermanew"), 247 South Beverly Drive, Suite 203, Beverly Hills, California 90212. Dermanew is the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in this Appeal.

III. STATUS OF CLAIMS

Claims 1-3, 5, 7 and 21-23 are pending in the application. The Patent Office has rejected claims 1-3, 5, 7 and 21-23. Claims 4, 6 and 8-20 are cancelled. Therefore, Appellant appeals the rejection of claims 1-3, 5, 7 and 21-23.

IV. STATUS OF AMENDMENTS

An amendment to Claim 5 was filed subsequent to the final rejection. The term "compositions" recited in original Claim 5 was amended to recite "composition." In the Advisory Action, the Patent Office indicates the amendment will be entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Embodiments of the Application provide for a composition for treating the skin. Page 1, paragraph [0002]. Independent Claim 1 recites the elements of a base comprising at least about twenty three percent by weight a moisturizer suitable for application to human skin, and plurality of abrasive particles having a particle size in

the range of 50 microns to 556 microns. Page 2, paragraph [0012]; Page 3, paragraph [0012]; Page 5, Example. Abrasive particles of the composition may include inorganic particles such as corundum, aluminum oxide, alumina, Al203 and magnesium oxide. Page 2, paragraph [0012]; Page 3, paragraph [0012]. The abrasive particles render the composition suitable as an exfoliator to improve the look and feel of an area of human skin. Page 3, paragraph [0013]. The particles may have an average particle size on the order of 34 microns to 556 microns. Page 3, paragraph [0012]. The abrasive particles may be suspended in the base in an amount from twenty to seventy percent by weight. Page 4, paragraph [0016]. The base may comprise as a principal component a moisturizer suitable for application to the human skin. Page 2, paragraph [0012]. Moisturizers are believed to reduce moisture loss from the skin and draw moisture from inner skin layers up into the outer skin layer. Page 3, paragraph [0014]. In one embodiment, the moisturizer includes a substance that attracts moisture to the top skin layer (a humectant). Page 3, paragraph [0014]. Suitable humectants may include a glycerin, propylene glycol, alpha hydroxyl acids, urea and lactic acid. Page 3, paragraph [0014]. The moisturizer may further include substances that tend to reduce water loss by creating a barrier such as petrolatum, mineral oil, lanolin or silicone derivatives. Page 4, paragraph [0014].

Independent Claim 5 recites an alternative embodiment, comprising a base in the form of a cream suitable for application to human skin, and a plurality of particles of corundum suspended in the base having an average particle size from 34 to 124 microns, and wherein the plurality of particles of corundum are at least thirty five percent weight of the composition. Page 4, paragraph, [0016] and [0017]. The abrasive particles may be present in the composition in an amount of about 5 to 100 grams per ounce of cream base, preferably 10 to 50 grams per ounce, and more preferably 10 to 20 grams per ounce. Page 4, paragraph [0017]. The base of the composition may be a liquid including a cleansing component, including but not limited to, soaps, salicylic

acid, a lauryl sulfate. Page 4, paragraph [0016]. In this embodiment, the composition may comprise 20 to 70 percent by weight corundum, 20 to 70 percent aloe gel, and five to 20 percent sodium lauryl sulfate. Page 4, paragraph [0016]. Other components may further be added to the base such as antioxidants, aromas/fragrances, vitamins, emulsifiers, toners, acids (e.g., glycolic acid), scrubs, serums, lotions, liquids, elixirs, sunscreens, and tonics. Page 4, paragraphs [0015], [0016]. For example in one embodiment, a cream moisturizer at approximately 14 grams microcrystals per ounce of cream may be used. In this embodiment, the composition may include alumina oxide (35%), purified water (14.288%), octyle palmitate (10%), safflower oil (10%), propylene glycol (2.9%), panthenol (1%), lecithin (0.5%), wheat germ oil (2%) among other components. Page 5, paragraph [0019]. The composition may be manipulated over an area of the skin for one to ten minutes or until the composition has been worked into the skin and the skin appears soft and smooth. Page 9, paragraph [0032]. In one embodiment where the composition comprises a moisturizer as a principal component, the composition may be worked in until substantially all of the moisturizer (and any other components) is taken up by the skin, such that the corundum is left on the surface of the skin. Page 9, paragraph [0032].

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues involved in this Appeal are as follows:

A. Whether Claims 1, 2, 3, 5, 7, 21, 22 and 23 are unpatentable under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement.

B. Whether Claims 1, 2, 3, 21, 22 and 23 are unpatentable under 35 U.S.C. §112, second paragraph, as being indefinite.

C. Whether Claims 1-3, 5, 7, 21, 22 and 23 are unpatentable under U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,290,976 issued to Messenger ("Messenger").

D. Whether Claims 1, 2, 21 and 22 are unpatentable under U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,294,179 issued to Lee et. al. ("Lee").

E. Whether Claims 1-3, 21, 22 and 23 are unpatentable under U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 3,092,111 issued to Saperstein ("Saperstein") or U.S. Patent No. 4,957,747 issued to Stiefel ("Stiefel").

F. Whether Claims 1-3, 5, 7, 21 and 22 are unpatentable under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,284,533 issued to Imamura ("Imamura").

G. Whether Claims 5 and 7 are unpatentable under 35 U.S.C. §103(a) as obvious over U.S. Pub. No. 2002/0090385 issued to Fox et. al. ("Fox").

H. Whether Claims 1-3, 21 and 22 are unpatentable under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,607,980 issued to McAtee et. al. ("McAtee").

I. Whether Claims 1, 2, 21 and 22 unpatentable under U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,756,081 issued to Wdowik ("Wdowik").

J. Whether Claims 1-3, 5, 7, 21-23 unpatentable under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 3,852,417 issued to McLaughlin ("McLaughlin") in view of Wdowik.

All of the claims do not stand or fall together. The basis for the separate patentability of the claims is set forth below.

VII. ARGUMENT

A. Overview of the Prior Art

1. Overview of Messenger

Messenger teaches a facial skin cleansing and reconditioning composition. See Messenger, Abstract. Messenger teaches that the composition is either a cream or a paste. See Messenger, col. 3, lines 5-7. A primary ingredient of the composition is an alpha alumina or corundum particle structure having facial skin abrading properties. See Messenger, col. 3, lines 8-11. The composition includes several additional ingredients including at least one emollient, at least one emulsifier, one or more preservatives and a diluent, preferably water. See Messenger, col. 3, lines 52-67. Messenger teaches the composition may further include titanium oxide to provide UV ray protection for the facial skin area. See Messenger, col. 4, lines 30-33.

2. **Overview of Lee**

Lee teaches a liquid skin washing composition for exfoliating the skin. See Lee, Abstract. Lee teaches the composition includes water, at least one surface active agent, suspended abrasive particles and a viscosifier. See Lee, col. 1, lines 56-60. Lee teaches the viscosity of the composition is typically that of a shower gel, i.e. in the range of 4000-8000 mPas. See Lee, Abstract. Lee further teaches water as a primary ingredient of the composition and characterizes components such as coloring agents, germicides, conditioning agents, emollients, humectants, moisturizers, anti-oxidants and preservatives as optional. See Lee, col. 4, lines 3-5. Lee teaches that the composition is to be applied to the skin, after the skin is washed with the composition, the composition is rinsed off the skin. See Lee, col. 6, lines 25-48.

Lee does not teach a composition having a base comprising at least about twenty three percent by weight a moisturizer suitable for application to a human skin. Lee further does not teach that the composition may be left on the skin after application.

3. **Overview of Saperstein**

Saperstein teaches a method for abrasion of the human skin for the treatment of acne. See Saperstein, col. 1, lines 10-11. Saperstein teaches the composition used in the method is a paste which includes a non-oleaginous detergent base having dispersed therein an inorganic abrasive. See Saperstein, col. 2, lines 65-68. Saperstein teaches that the composition may be prepared by blending detergents and emollients in water to produce a smooth, creamy paste. See Saperstein, col. 7, lines 23-25. In particular, Saperstein teaches the composition may include a mixture of soaps, i.e. sodium laurate,

sodium myristate, and sodium stearate with a synthetic surface active agent, i.e. sodium lauryl sulfate. See Saperstein , col. 7, lines 13-22. The composition further includes three different emollients, i.e. lanolin (0.5%), polyethylene glycol (10.1%) and glycerine (2.8%), water (60.6%) and abrasives. See Saperstein, col. 7, lines 1-40. Saperstein teaches the composition is applied to the skin with a rotary motion for approximately ten counts, and removed from the skin by the use of a wash cloth and hot water. See Saperstein, col. 8, lines 42-57. Saperstein teaches the application and removal requires no more than two or three minutes. See Saperstein, col. 8, lines 57-59. Saperstein cautions if the skin becomes irritated, the routine should be interrupted for a day or so. See Saperstein, col. 8, lines 63-65. Saperstein teaches that the objective of the treatment is to keep the sebum washed off the skin. See Saperstein , col. 9, lines 59-60.

Saperstein does not teach a composition having a base comprising at least about twenty three percent by weight a moisturizer suitable for application to a human skin. Saperstein further does not teach that the composition may be left on the skin after application.

4. Overview of Stiefel

Stiefel teaches a fluid topical composition for treating aged skin. See Stiefel, Abstract. Stiefel teaches that the composition contains a suspension of fine particles of a non-absorbable aluminum oxide abrasive in an aqueous base of sodium cocoisethionate, at least one emollient, and a suspending agent. See Stiefel, Abstract. Stiefel teaches the composition may further include water. See Stiefel , col. 1, lines 62-

63. Stiefel further teaches minor dermatitis may appear during use of the composition. See Stiefel, col. 2, lines 10-12.

Stiefel does not teach a composition having a base comprising at least about twenty three percent by weight a moisturizer suitable for application to a human skin. Stiefel further does not teach that the composition may be left on the skin after application.

5. Overview of Imamura

Imamura teaches a liquid cleanser composition including abrasive particles. See Imamura, Abstract. Imamura teaches the composition includes a polyacrylic acid, a hydrotope, a surfactant, a water-insoluble abrasive and water. See Imamura, col. 7; col. 8, lines 1-30. Imamura further teaches the composition has a low viscosity of less than 5000 cps. See Imamura, col. 1, lines 52-55. Imamura teaches such low viscosity liquid composition is desirable because higher viscosity compositions have poor fluidity and are not easy to dispense from a container. See Imamura, col. 1, lines 35-40.

Imamura does not teach a base comprising at least about twenty three percent by weight a moisturizer suitable for application to human skin. Imamura does not teach a base in the form of a cream suitable for application to human skin. Imamura does not teach the composition may be left on the skin after application.

6. Overview of Fox

Fox teaches a composition and method for removing an epidermal portion of the skin by microdermabrasion with a crystalline emulsion. See Fox, Abstract. Fox teaches the composition includes crystals coated with methicone and a carrier. The user gently

rubs the composition on the face in a circular motion ten to fifteen times, the face is then rinsed with warm water and patted dry. See Fox, col. 2, paragraph [0028].

Fox does not teach a base in the form of a cream for application to human skin.

7. Overview of McAtee

McAtee teaches a topical composition to improve skin feel. See McAtee, Abstract. McAtee teaches the composition includes an amphoteric surfactant (0.1-20%), cationic surfactant (0.1-15%), water (45-99.7%). See McAtee, col. 3, lines 15-30. McAtee teaches the composition may include additional components such as vitamins, preservatives, emulsifiers, humectants, moisturizers, etc. See McAtee, col. 10, lines 1-40. In particular, McAtee teaches the composition may contain one or more humectants or moisturizers at a level of from about 0.1-20%, more preferably from about 0.5% to about 15%, and most preferably from about 1% to about 10%. See McAtee, col. 13, lines 40-46. Furthermore, the composition may include insoluble particles. See McAtee, col. 13, lines 65-67.

McAtee does not teach a composition having a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin.

8. Overview of Wdowik

Wdowik teaches a shaving composition containing particulate additives. See Wdowik, Abstract. Wdowik discloses the composition may include potassium stearate, sodium stearate, lauric acid diethanolamide (1.60%), mineral oil (17%), stearic acid (0.13%), coconut fatty acid (0.68%), glycerine (3.2%), PVP (0.12%), perfume, water (57.58%), propellant and particulate additive (3%) about 75 microns in size. See

Wdowik, col. 6, lines 1-21. Wdowik teaches the shaving composition provides for a close shave and improves skin smoothness. See Wdowik, col. 7, lines 52-66.

Wdowik does not teach a composition having a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin. Wdowik does not teach the composition may be left on the skin after application.

9. **Overview of McLaughlin**

McLaughlin teaches a shave composition for dispensing from a valved pressure container. See McLaughlin, Abstract; col. 1, lines 42-45. McLaughlin teaches the composition includes a water-soluble soap, a liquid oil material, glycerine or propylene glycol humectant and a water-soluble sodium, potassium or triethanolammonium cocoate soap. See McLaughlin, col. 1, lines 55-68; col. 2, lines 1-7. McLaughlin teaches the composition enhances the shaving operation in that it lubricates the face so that minimal razor drag is noticed. See McLaughlin, col. 2, liens 10-14.

McLaughlin does not teach a composition comprising both a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin and a plurality of abrasive particles in the range of 50 microns to 556 microns. McLaughlin does not teach a composition having a base in a form of a cream suitable for application to human skin and a plurality of particles of corundum, wherein the plurality of particles of corundum are at least thirty five percent by weight of the composition. McLaughlin does not teach a composition that may be left on the skin after application.

B. **Rejection of Claims 1, 2, 3, 5, 7 21, 22 and 23 Under 35 U.S.C. § 112, first paragraph**

The Patent Office rejects claims 1-3, 5, 7 and 21-23 under 35 U.S.C. §112, first paragraph. According to the Patent Office, Claims 1-3 fail the written description requirement because the Application fails to provide a description of a composition in which a single agent that is a moisturizer is present in an amount of about 23 percent. The Patent Office believes Claims 5, 7 and 23 also fail the written description requirement because the Application fails to describe an example of a composition containing at least 35 percent corundum. Finally, the Patent Office believes Claims 5 and 7 fail the written description requirement because the Application does not disclose an average particle size of corundum of 124 microns.

1. **Moisturizer**

In terms of the definition, the Application describes moisturizers in the following way:

> In one embodiment, the composition comprises a base that is capable of suspending the plurality of abrasive particles within the base. One particular component, that in one embodiment is included as a principal component in the base, is a moisturizer. Moisturizers are believed to reduce water loss from the skin and draw moisture from inner skin layers up into the outer skin layer. In this regard, in one embodiment, the moisturizer includes a substance that attracts moisture to the top skin layer (a humectant). Suitable humectants include glycerin, propylene glycol, alpha hydroxy acids, urea, and lactic acid. The moisturizer may also include substances that tend to reduce water loss by creating a barrier. Such substances include petrolatum, mineral oil, lanolin and silicone derivatives.

Application, at 3, paragraph 14.

To the extent that the Patent Office is requiring that at least one of a component that has a property of a moisturizer be present in the composition in at least about 23%, Appellant believes that it is not a requirement of the claims. Claim 1, for example, does not require that only a single component that has a property of a moisturizer total at least about 23% by weight of the base.

Paragraph 19 of the Application provides one example of a composition, including octyl palmitate (10%), safflower oil (10%), and propylene glycol (2.9%), each of which has a property of a moisturizer. The composition also includes panthenol (1%), which has humectant properties.

In terms of moisturizers, the Patent Office believes water may have moisturizing properties with respect to human skin. Appellant does not believe this is necessarily a correct statement and asserts that the Patent Office has not provided any evidence that water has a moisturizing property in a composition comprising a base suitable for application to human skin.

2. <u>23% Moisturizer and 35% Corundum</u>

The Patent Office believes the Application does not support a composition, including at least 23% with respect to the moisturizer and at least 35% corundum by weight as specified in claims 1-3 and 21-23 and 5 and 7, respectively. As noted in the Response to Final Office Action, the Patent Office has the initial burden of presenting evidence for reasons why a person skilled in the art would not recognize in the specification disclosure, a description of the invention defined by the claims. The Patent Office has not done this for either at least 23% with respect to the moisturizer of claims

1-3 and 21-23 or at least 35% with respect to corundum of claims 5 and 7. The Patent Office's "support" is paragraphs 16 and 17 of the Application where the Patent Office says the ranges of "at least 23%" moisturizer and "at least 35%" corundum are not supported.

The example provided at paragraph 19 describes one embodiment of a composition, including 35% aluminum oxide and at least 23% moisturizers (see above discussion).

Paragraph 16 describes an embodiment of the composition that includes a cleansing component. In that embodiment, the composition includes 20-70% corundum, 20-70% aloe gel and 5-20% sodium lauryl sulfate.

Paragraph 17 describes another example of corundum in a cream moisturizer base. The corundum is present in one embodiment in an amount of about 5-100 grams per ounce of cream. In another embodiment, 10-50 grams per ounce. And, in another embodiment, 10-20 grams per ounce of cream.

At least 23 percent moisturizer and at least 35 percent abrasive particles in a composition is clearly taught by the Application. To the extent the Patent Office believes the claims must specify an upper limit for a moisturizer or the abrasive particles, the written description requirement of 35 U.S.C. §112, first paragraph, does not mandate such requirement. Rather, to satisfy the written description requirement the specification must "describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." See MPEP(I).

Taken collectively, paragraphs 16-19 of the Application provide three examples (embodiments) of compositions in full, clear and exact terms to enable a person skilled in the art (e.g. a formulation chemist) to make a composition including a base comprising at least 23 percent by weight a moisturizer and/or comprising particles of corundum that are at least 35 percent by weight of the composition.

3. **Particle Size**

The Patent Office believes there is no support in the Application for an average particle size being 124 microns as recited in claims 5 and 7. The Patent Office again cites *In re Lukach* and *In re Smith*. The Patent Office also cites *In re Wertheim (II)* for a holding that where a limitation was within a broader disclosure of a parent case, the limitation constituted new matter and was relevant because the limitation avoided the prior art. Appellant believes this has no relevance to the 35 U.S.C. §112, first paragraph analysis required here. It cannot be relevant for purposes of 35 U.S.C. §112, first paragraph, that a limitation was added to avoid the prior art. *In re Wertheim (II)* was concerned with the priority date of anticipatory matter with respect to related applications.

Appellant maintains that *In re Wertheim (I)* is directly relevant to whether an average particle size of 124 microns is supported by the specification.

In re Wertheim (I) is a precedent subsequent in time to both *In re Lukach* and *In re Smith*. *In re Wertheim (I)* directly addresses the holdings of both of these cases and provides a guiding discussion of the manner in which a written description requirement should be determined. See *In re Wertheim (I)* at 96. As noted by the Court, in *In re Wertheim (I)*, *In re Lukach* appropriately sets forth the proposition that "the

invention claimed did not have to be described in *ipsis verbis* in order to satisfy the description requirement of section 112." See *In re Lukach* at 796. *In re Lukach, In re Smith,* and *In re Wertheim (I)* all clearly set forth that the manner in which a written description requirement should be analyzed on a case by case basis with close attention to the facts of the case to determine whether an application conveys to those skilled in the art information that this Appellant invented the subject matter of the claims. See *In re Smith* at 683 ("precisely how this description must come to comply with section 112 must be left to case by case development") and *In re Werthheim (I)* at 97 ("mere comparison of ranges is not enough, nor are mechanical rules a substitute for the analysis of each case on its facts to determine whether an application conveys to those skilled in the art the information that the Appellant invented the subject matter of the claims").

The Patent Office's statement that the ruling in *In re Wertheim (I)* is based on the fact that there was a specific embodiment of 36 percent and the minimum of the claimed range was 35 percent is simply inaccurate. In fact, the claims in *In re Wertheim (I)* specifically claims 2, 37 and 38 claimed a range of between 35 percent and 60 percent which was supported by a broad range in the description of 25 percent to 60 percent. See *In re Wertheim* at 98 ("claims 2, 37, and 38 which claim a solids content range of 'between 35 percent and 60,' present a different question. They clearly claim a range within the described broad range of 25 percent to 60 percent solids; the question is whether, *on the facts* the PTO has presented sufficient reason to doubt the broader described range also describes the somewhat narrower claimed range. We note that

there is no evidence, and the PTO does not contend otherwise, that there is in fact any distinction, in terms of operability of Appellant's process or of the achievement of any desired result between the claimed lower limit of solids content and that disclosed in the Swiss application.") Thus, the facts in *In re Wertheim* are directly analogous to the facts of the present case where the Appellant claims ranges that fall directly within broader ranges described in the Application. Further, the narrow ranges in the present Application have the same ability to produce the same desired results as the broader range in contrast to the fact scenario of *In re Lukach*, which the Patent Office cites against the Application where the Appellant relies on a single example ratio of 2.6 in the specification to support a claim to a range of ratios between 2.0 and 3.0. See *In re Lukach* at 797. Thus, the proper analysis in this case is to look closely at the actual circumstances of the description in relation to the claims to determine if one of ordinary skill in the art would understand that the Appellant possessed the invention at the time of filing. In this regard, the case of *In re Wertheim (I)* is directly on point with the facts of the Application. And thus for the same reasons set forth by the Court in *In re Wertheim (I)*, claims 1 and 5 meet the written description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, reconsideration and withdrawal of the written description requirement rejection are requested.

Appellant believes all the Patent Office's issues were addressed with respect to the 35 U.S.C. §112, first paragraph rejection and controverted. In view of the foregoing, Appellant respectfully requests the rejection to claims 1-3, 5, 7 and 21-23 under 35 U.S.C. §112, first paragraph be overturned.

C. **Rejection of Claims 1, 2, 3, 21, 22 and 23 Under 35 U.S.C. § 112, second paragraph**

The Patent Office rejects claims 1-3 and 21-23 under 35 U.S.C. §112, second paragraph as indefinite. Specifically, the Patent Office cites to the phrase, "about twenty three percent". The Patent Office cites *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 18 USPQ2D 1016, 1030-31 (CAFC 1991). Amgen* dealt with a claim term of "at least about 160,000 IU/AU" to define a specific activity limitation held to be indefinite by a lower court because (1) bioassays provide an imprecise form of measurement with a range of error and (2) there is a range of error already inherent in the specific activity limitation. Thus, the "about 160,000 IU/AU" limitation did not distinguish the invention over close prior art of 120,000 IU/AU, or permit one to know what specific activity values below 160,000 IU/AU might constitute infringement. The Court of Appeals supported the lower court holding because there was nothing in the specification, prosecution history, or prior art providing any indication as to what range of specific activity is covered by the term, "about" and because no expert testified as to a definite meaning for the term in the context of the prior art.

In this case, the Application describes amounts of moisturizer in a base in terms of whole numbers (e.g., 20-70% aloe gel). The individual ingredients provided in the example in paragraph 19 having moisturizing properties are represented in terms of percentages to a first decimal (tenths). Appellant does not believe that the measurement of ingredients, such as octyl palmitate, safflower oil, or propylene glycol

by formulation chemists of ordinary skill in the art of manufacturing compositions such as claimed, have an inherent large range of error.

In view of the foregoing, Appellant respectfully requests that the rejection to claims 1-3 and 21-23 under 35 U.S.C. §112, second paragraph be overturned.

D. Rejection of Claims 1, 2, 3, 5, 7, 21, 22 and 23 Under 35 U.S.C. § 103 as Obvious over Messenger

The Patent Office rejects claims 1-3, 5, 7 and 21-23 under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Messenger. In a previous response, Appellant submitted an Affidavit under 37 CFR §1.131 to overcome the rejection of Messenger. The above-referenced Affidavit is submitted herewith for the convenience of the Patent Office as Exhibit C along with Exhibits A and B referenced in the Affidavit. The Patent Office believes the Affidavit does not show a composition including a base comprising at least about 23 percent by weight a moisturizer and that the abrasive particles comprise at least 35 percent.

A review of the Affidavit submitted under 37 CFR §1.131 shows that there is at least 22.3 percent of components in the base that can be classified as moisturizers: panethenol (0.30); propylene glycol (2.00); dehyhag wax (5.00); safflower oil (6.00); octyl palmitate (7.00); and wheat germ oil (2.00). Appellant believes this is sufficient to establish invention of the subject matter of Claims 1-3 and 21-23 prior to the effective date of Messenger. With respect to the amount of abrasive particles, the Affidavit sets forth a composition including 50 percent particles, which is at least 35 percent of a composition as set forth in Claims 5, 7 and 23.

The Patent Office also argues that with respect to Claims 1-3, 5, 7 and 21-23, the Affidavit is not commensurate in scope to the extent the claimed invention shows conception and reduction to practice of the invention prior to the effective date of Messenger. Absent Messenger claiming the same invention, Messenger may be eliminated as a prior art reference under 35 U.S.C. §102(e).

Appellant respectfully submits Claims 1-3, 5, 7 and 21-23 are separately patentable over Messenger and requests the rejection of Claims 1-3, 5, 7 and 21-23 under 35 U.S.C. §102 or, in the alternative, 35 U.S.C. §103 be overturned.

E. Rejection of Claims 1, 2 and 22 Under 35 U.S.C. §102 as anticipated by or, in the alternative, Under 35 U.S.C. § 103 as Obvious over Lee

Anticipation may only be established if "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Similarly, to establish a *prima facie* case of obviousness, the Patent Office must show the cited references, combined, teach or suggest each of the elements of a claim. In regard to Claim 1, Lee fails to teach or suggest a composition comprising at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin." The Patent Office characterizes water as a moisturizer and on this basis concludes Lee teaches at least about 23% by weight a moisturizer because Lee teaches water in an amount greater than 20%. The Patent Office cites the *American Heritage Dictionary of the English Language*, Fourth Edition (2000) in support stating "moisturizer" means a cosmetic

lotion or cream applied to the skin to counter dryness." The Patent Office suggests since water provides moisture, and is present in the composition in an amount greater than 20% it falls within the scope of the above-recited limitation. Appellant respectfully disagrees with the Patent Office's characterization.

The Patent Office's suggestion that water is a moisturizer is not supported by the teachings of Lee. Lee expressly lists several optional components of a composition including "conditioning agents, emollients, humectants, moisturizers [sic.], antioxidants and preservatives." See Lee, col. 4, lines 3-5. "Water" is recited as an element of Claim 1 and a component in each of the examples taught by Lee. Accordingly, water does not fall within the category of optional components (e.g., moisturizers) recited by Lee. Accordingly, the language of Lee clearly shows water is just that, water, and not understood to be or characterized as, a moisturizer. In addition, the teachings of U.S. Patent No. 5,219,571 of Wise (disposing bentonite in lipophilic agent to percutaneously absorb into skin) and U.S. Patent No. 5,607,980 of McAtee (using amphoteric surfactants to deliver products to the skin), among other cited references, indicates that water does not have a property of a moisturizer to skin. Thus, upon viewing the teachings of Lee and the other cited references, one of ordinary skill in the art would not understand water to be a moisturizer as suggested by the Patent Office.

Moreover, nowhere within the definition cited by the Patent Office is it suggested water is a moisturizer. Water is neither a lotion nor cream. In fact, it is well known that water evaporates from the surface of the skin, causing drying of the

skin and thus providing the need for a moisturizer. In addition, the fact that water may be characterized as "moisture" does not mean it is also a "moisturizer." The term "moisture" is defined as a "state or quality of being damp." *The American Heritage Dictionary of the English Language*, Fourth Edition (2000). See Exhibit D attached herewith. Certainly the Patent Office would not characterize any material falling within this definition as a moisturizer. Similarly, the Patent Office has not indicated how water comes within the examples of moisturizers described in the Application, e.g., those that attract moisture to the top skin layer or those that tend to reduce water loss by creating a barrier on the skin. The Patent Office alleges since the claimed moisturizer may be a combination of components, water plus surfactants, hectorite and/or xantham gum fall within the scope of the term. Appellant disagrees and submits in any event such a combination would not meet the limitations of Claim 1. If water plus the other components of the composition are the moisturizer, the Patent Office has not pointed to, and Appellant is unable to discern, a base comprising at least about twenty three percent by weight the moisturizer.

Thus, at least for the reasons discussed above, the Patent Office has failed to show that Lee teaches or suggests at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin" as recited in Claim 1. Accordingly, Appellant respectfully submits, the relied upon reference fails to teach or suggest every element of Claim 1. Since each and

every element of Claim 1 is not taught or suggested by the reference of record, neither anticipation nor a *prima facie* case of obviousness have been established.

For the foregoing reasons, the Patent Office has failed to establish that Lee teaches or suggests each of the elements of Claim 1 or its dependent claims. Accordingly, Appellant respectfully submits Claims 1, 2 and 22 are separately patentable over Lee and requests the rejection of Claims 1, 2 and 22 under 35 U.S.C. §102, or in the alternative, 35 U.S.C. §103 be overturned.

F. Rejection of Claim 21 Under 35 U.S.C. §102 as anticipated by, or in the alternative, Under 35 U.S.C. § 103 as Obvious over Lee

In regard to Claim 21, this claim depends from independent Claim 1 and incorporates the limitations thereof. Thus, at least for the reasons mentioned in regard to Claim 1, the Patent Office has failed to establish, anticipation or a *prima facie* case of obviousness over Lee for Claim 21.

In addition, Claim 21 is separately patentable over Lee because it teaches the additional element of "wherein the composition may be left on the skin after application." The Patent Office alleges Appellant has the burden of "showing that the composition in Lee is toxic if left on the skin." See Final Action, page 9, first paragraph. Appellant respectfully traverses the Patent Office's rejection for at least the following reasons.

Before placing the burden alleged above on the Appellant, the Patent Office has the initial burden of establishing a *prima facie* case of obviousness by showing each and every element of the claims are taught by the reference. See MPEP §2143.

The Patent Office has failed to meet this initial burden. As recognized by the Patent Office, Lee fails to expressly state the composition is capable of being left on the skin. The teachings of Lee do not imply the composition may be left on the skin, nor would this feature be inherent. In fact, Lee suggests just the opposite. Lee teaches a composition for exfoliating skin. It is only desirable to exfoliate debris and dead skin cells at the surface of the skin to give the skin a smooth fresh feel. See Lee, col. 5, lines 14-35. Lee teaches this is achieved by application and subsequent removal of the composition. Certainly leaving an abrasive composition on the skin would not result in a smooth fresh feel. Instead, leaving the composition on the skin is likely to result in a gritty feel to the skin. Moreover, the composition may penetrate the upper skin layers and possibly remove live skin layers leaving the skin raw and open to infection. Thus, in as much as the composition may damage the skin if left on, it is not inherently capable of meeting the limitation of Claim 1. Moreover, the Patent Office may not rely on "common knowledge" without evidentiary support to teach this element since, for the above reasons, the effects of leaving the composition taught by Lee on the skin are not capable of instant and unquestionable demonstration. See MPEP §2144.03(A). Lee may be suitable for application to the skin, but not for being left on the skin after application as required by Claim 21.

Lastly, even if the Patent Office has set forth a *prima facie* case, Appellant's burden is not one of showing the composition of Lee is toxic if left on the skin as suggested by the Patent Office. The cases cited by the Patent Office do not suggest such a burden and in any event are distinguishable from the instant case. In both *In*

re Casey, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963), at issue were structural claims. Accordingly, the court could discern from viewing the structure whether the structures were capable of meeting the terms of Appellant's claims. In contrast, the instant Application and Lee are directed toward compositions comprising a variety of ingredients. In contrast to *Casey* and *Otto*, the actual effect of the composition in Lee when left on the skin is virtually unknown until such a test is actually performed. Lee does not describe any such testing or otherwise indicate what the results of such a test would be. Thus, neither *Casey* nor *Otto* are instructive in the instant case.

Thus, for these additional reasons, the Patent Office has failed to establish anticipation, or in the alternative, a *prima facie* case of obviousness for Claim 21 based on Lee. Accordingly, Claim 21 is separately patentable over Lee. Appellant respectfully requests the rejection of Claim 21 under 35 U.S.C. §102 or, in the alternative, 35 U.S.C. §103 be overturned.

G. Rejection of Claims 1, 2, 3, 22 and 23 Under 35 U.S.C. §102 as anticipated by or, in the alternative, Under 35 U.S.C. § 103 as Obvious over Saperstein

In regard to Claim 1, Saperstein fails to teach or suggest a composition comprising at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin." The Patent Office characterizes water as a moisturizer and alleges Saperstein teaches this element because Saperstein teaches a composition including the components of lanolin,

polyethylene glycol, glycerine and water, where water is in an amount greater than 23%. Appellant respectfully disagrees with the Patent Office's characterization of water as a moisturizer for the reasons previously discussed and the additional reasons set forth below.

The Patent Office states Appellant's specification teaches a moisturizer may include humectants, glycerine, propylene glycol, lanolin and silicon derivatives. The Patent Office alleges since Saperstein teaches a composition including lanolin, polyethylene glycol, glycerine and water, the combination meets Appellant's claimed limitation of "a base comprising at least about twenty three percent by weight a moisturizer." Although Appellant's specification may be used to shed light on the meaning of claim terms, it may not be used to read limitations into the claims or define claim terms in a manner inconsistent with the meaning suggested throughout the specification. As pointed out by the Patent Office, Appellant's specification offers examples of moisturizers. The specification further describes moisturizers as those that attract moisture to the top skin layer or those that tend to reduce water loss by creating a barrier on the skin. Nowhere does Appellant characterize water as a moisturizer nor does it fall within the description in the specification. Accordingly, contrary to the Patent Office's assertion, Appellant's specification does not support the conclusion that water is a moisturizer. Certainly, one skilled in the art would not understand water to reduce further water loss from the skin or draw moisture from inner skin layers. Accordingly, water may not be characterized as a moisturizer as claimed in the instant Application. Accordingly, even if it were possible to combine the lanolin, polyethylene

glycol and glycerine of Saperstein to teach Appellant's claimed moisturizer, Saperstein teaches in Example 4 these components combined only add up to 13.4% by weight of the composition. See Saperstein, col. 7, lines 1-10. Accordingly, the composition of Saperstein does not "appear" to fall within the scope of the claimed invention as stated by the Patent Office. See Final Office Action, page 10, first paragraph. In any event, neither anticipation nor a prima facie case of obviousness may be established based on a standard of what a reference "appears" to teach.

Thus, at least for the reasons discussed above, the Patent Office has failed to show that Saperstein teaches or suggests at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin" as recited in Claim 1. Accordingly, Appellant respectfully submits, the relied upon reference fails to teach or suggest every element of Claim 1. Since each and every element of Claim 1 is not taught or suggested by the reference of record, neither anticipation nor a *prima facie* case of obviousness have been established.

For the foregoing reasons, the Patent Office has failed to establish that Saperstein, teaches or suggests each of the elements of Claim 1 or its dependent claims. Accordingly, Appellant respectfully submits Claims 1, 2, 3, 22 and 23 are separately patentable over Saperstein and requests the rejection of Claims 1, 2, 3, 22 and 23 under 35 U.S.C. §102 or, in the alternative, 35 U.S.C. §103 be overturned.

H. Rejection of Claim 21 Under 35 U.S.C. §102 as anticipated by, or in the alternative, Under 35 U.S.C. § 103 as Obvious over Saperstein

In regard to Claim 21, this claim depends from independent Claim 1 and incorporates the limitations thereof. Thus, at least for the reasons mentioned in regard to Claim 1, the Patent Office has failed to establish anticipation or a *prima facie* case of obviousness over Saperstein for Claim 21.

In addition, Claim 21 is separately patentable over Saperstein because it teaches the additional element of "wherein the composition may be left on the skin after application. The Patent Office alleges Appellant has the burden of "showing that the composition in Saperstein is toxic if left on the skin." See Final Office Action, page 10. Appellant respectfully traverses the Patent Office's rejection for at least the following reasons.

The Patent Office has failed to established its initial burden of showing this feature is implicitly or inherently found within Saperstein. Saperstein, in fact, teaches just the opposite. Saperstein expressly states that the composition is to be applied for no more than "ten counts" and then removed from the skin. See Saperstein, col. 8, lines 53-57. Saperstein further teaches that the objective of the treatment is to keep the resulting sebum washed off the skin. See Saperstein, col. 9, lines 59-60. In addition, Saperstein cautions that using the composition according to this routine may result in irritation and scaling and suggest the user discontinue use of the composition for a day or so. See Saperstein, col. 8, lines 61-67. Accordingly, Saperstein strongly implies the composition may cause damage to the skin if left on. Moreover, if the Patent Office

believes that it is common knowledge that the composition taught by Saperstein may be left on the skin after application, this fact must be supported by documentary evidence since it is certainly not capable of instant and unquestionable verification.

Thus, for these additional reasons, the Patent Office has failed to establish anticipation, or in the alternative, a *prima facie* case of obviousness for Claim 21 based on Saperstein. Accordingly, Claim 21 is separately patentable over Saperstein. Appellant respectfully requests the rejection of Claim 21 under 35 U.S.C. §102, or in the alternative, 35 U.S.C. §103 be overturned.

I. Rejection of Claims 1, 2, 3, 22 and 23 Under 35 U.S.C. §102 as anticipated by or, in the alternative, Under 35 U.S.C. § 103 as Obvious over Stiefel

In regard to Claim 1, Stiefel fails to teach or suggest a composition comprising at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin." The Patent Office characterizes water as a moisturizer and alleges Stiefel teaches this element because Stiefel teaches a composition including the components of polyethylene glycol, dimethicone, glycerine and water, where water is in an amount greater than 23%. Appellant respectfully disagrees with the Patent Office's characterization of water as a moisturizer for the reasons previously discussed and the additional reasons set forth below.

As previously discussed, Appellant's specification does not support the conclusion that water is a moisturizer. Moreover, Stiefel itself does not support the Patent Office's characterization. In the portion of Stiefel cited by the Patent Office,

Stiefel categorizes the composition ingredients as either emollients, soap formers or antioxidant/preservative. Water is listed in an entirely separate category from the compositions the Patent Office lists as moisturizers (e.g., polyethylene glycol, dimethicone and glycerine). Moreover, Claims 5 and 7 of Stiefel group polyethylene glycol and dimethicone together, water is not included in this group.

Even if it were possible to combine the polyethylene glycol, glycerine and dimethicone of Stiefel to teach Appellant's claimed moisturizer in an amount of at least about twenty three percent by weight of the base, Stiefel teaches in Examples 1 and 2 that these components combined, at the most, only add up to 7.06% by weight of the composition. See Stiefel, col. 2, lines 15-37, Example 1. Accordingly, the composition of Stiefel does not "appear" to fall within the scope of the claimed invention as stated by the Patent Office. In any event, neither anticipation nor a prima facie case of obviousness may be established based on what a reference "appears" to teach as suggested by the Patent Office.

Thus, at least for the reasons discussed above, the Patent Office has failed to show that Saperstein teaches or suggests at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin" as recited in Claim 1. Accordingly, Appellant respectfully submits, the relied upon reference fails to teach or suggest every element of Claim 1. Since each and every element of Claim 1 is not taught or suggested by the reference of record, neither anticipation nor a *prima facie* case of obviousness have been established.

For the foregoing reasons, the Patent Office has failed to establish that Stiefel, teaches or suggests each of the elements of Claim 1 or its dependent claims. Accordingly, Appellant respectfully submits Claims 1, 2, 3, 22 and 23 are separately patentable over Stiefel and requests the rejection of Claims 1, 2, 3, 22 and 23 under 35 U.S.C. §102 or, in the alternative, 35 U.S.C. §103 be overturned.

J. Rejection of Claim 21 Under 35 U.S.C. §102 as anticipated by or, in the alternative, Under 35 U.S.C. § 103 as Obvious over Stiefel

In regard to Claim 21, this claim depends from independent Claim 1 and incorporates the limitations thereof. Thus, at least for the reasons mentioned in regard to Claim 1, the Patent Office has failed to establish, anticipation or a *prima facie* case of obviousness over Stiefel for Claim 21.

In addition, Claim 21 is separately patentable over Stiefel because it teaches the additional element of "wherein the composition may be left on the skin after application." The Patent Office alleges Appellant has the burden of showing that the composition in Stiefel is toxic if left on the skin. See Final Action, page 10. Appellant respectfully traverses the Patent Office's rejection for at least the reasons previously discussed. Namely, the Patent Office has not established its initial burden of showing this feature is expressly, implicitly or inherently found within Stiefel. Moreover, if the Patent Office believes that it is common knowledge that the composition taught by Stiefel may be left on the skin after application, this fact must be supported by documentary evidence.

Thus, for these additional reasons, the Patent Office has failed to establish anticipation, or in the alternative, a *prima facie* case of obviousness for Claim 21 based on Stiefel. Accordingly, Claim 21 is separately patentable over Stiefel. Appellant respectfully requests the rejection of Claim 21 under 35 U.S.C. §102 or, in the alternative, 35 U.S.C. §103 be overturned.

K. Rejection of Claims 1, 2, 3 and 22 Under 35 U.S.C. § 103 as Obvious over Imamura

In regard to Claim 1, Imamura fails to teach or suggest a composition comprising at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin." The Patent Office again reaches its conclusion of obviousness by including water as a moisturizer suitable for application to human skin. For at least the reasons previously discussed, water is not a moisturizer and Imamura fails to teach or suggest any other component of the base which is a moisturizer and present in an amount of at least about twenty three percent by weight of the base.

Thus, at least for the reasons previously discussed, the Patent Office has failed to show that Imamura teaches or suggests at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin" as recited in Claim 1. Accordingly, Appellant respectfully submits, the relied upon reference fails to teach or suggest every element of Claim 1. Since each and every element of Claim 1 is not taught or suggested by the reference of record, a *prima facie* case of obviousness has not been established.

For the foregoing reasons, the Patent Office has failed to establish that Imamura, teaches or suggests each of the elements of Claim 1 or its dependent claims. Accordingly, Appellant respectfully submits Claims 1, 2, 3 and 22 are separately patentable over Imamura and requests the rejection of Claims 1, 2, 3 and 22 under 35 U.S.C. §103 be overturned.

L. Rejection of Claims 5 and 7 Under 35 U.S.C. § 103 as Obvious over Imamura

In regard to Claim 5, Imamura fails to teach or suggest at least the element of "a base in a form of a cream suitable for application to human skin" as recited in Claim 5. The Patent Office alleges the composition having a viscosity of less than 5000 cps as taught by Imamura is a cream. Imamura, however, fails to identify the composition as a cream. Instead Imamura suggests just the opposite, characterizing the composition as a "liquid cleanser composition having a low viscosity of less than 5000 cps." See Imamura, col. 1, lines 50-55. Imamura distinguishes the composition from dispersions having "extremely high viscosities, i.e., higher than 5000 cps" stating such dispersions have poor fluidity and are not easy to dispense from a container. See Imamura, col. 1, lines 50-55. Certainly one of ordinary skill in the art would not understand the low viscosity, liquid cleaner taught by Imamura to be a cream.

Moreover, the term "cream" must be given its plain meaning. See MPEP §2111.01. In response to the Office Action dated March 11, 2004, Appellant submitted the article titled "Topical Drug Bioequivalence: FDA Revised Strategy to be Presented to Committee; Reporting CMC Changes Also on Agenda" wherein a cream is identified

as having a viscosity greater than 30,000 cps while a lotion has a viscosity less than 30,000 cps. The document entitled "Topical Drug Bioequivalence: FDA Revised Strategy to be Presented to Committee; Reporting CMC Changes Also on Agenda" is submitted herewith as Exhibit E. Appellant further submitted the definition of cream provided by cosmetic industry glossary at www.corycosmetics.com/cosmetic_ingredients_glossary.htm defining cream as "a preparation for the skin to impart moisture. A cream is usually thicker and more emollient 'smoother and softer' than a lotion." A copy of the definition provided by cosmetic industry glossary is submitted herewith as Exhibit F. Appellant further submitted an article on viscosity from the website www.liquidcontrol.com indicating that a compound having a viscosity in the range of 600 to 1000 cps is found in the same category as pure motor oil. A copy of the article from the website www.liquidcontrol.com is submitted herewith as Exhibit G. In contrast, a cream, such as sour cream, is shown to have a viscosity of 100,000 cps. The above referenced documents are resubmitted herewith for the Patent Office's convenience.

In light of the above evidence and the teachings of Imamura, it is clear that one of ordinary skill in the art would not understand a liquid composition which can be "shaken out" of a container to be a "cream." Nevertheless, the Patent Office maintains that the term "cream" is understood to include compositions having viscosities less than 5,000 cps and submits a definition from the website of a company specializing in polyurethane grouts and epoxies. Certainly, the definition provided by a website specializing in resin materials does not show what one of ordinary skill in the art would

understand the viscosity of a cosmetic cream to be. Moreover, the Patent Office suggests the FDA article is not persuasive because the FDA was inquiring whether it was reasonable to distinguish lotions from creams based on viscosity. The FDA's inquiry, however, does not change the fact that the FDA suggested creams have a viscosity greater than 30,000 cps. Moreover, the Patent Office has not submitted evidence showing the definition was found unacceptable or otherwise revised by the FDA. Certainly the FDA is a more credible source than an online resin glossary.

Appellant further submits the patent cited by the Patent Office, U.S. Patent No. 6,284,257 (the '257 patent) disclosing creams having viscosities less than 5,000 cps is not consistent with the common usage of the term cream. As previously discussed, a cream having a viscosity less than 5,000 cps would put the cream in the same category as pure motor oil. One of ordinary skill in the art would understand cream to have a greater viscosity than motor oil. Moreover, Appellant further directs the Patent Office's attention to U.S. Patent No. 6,696,068 issued to Crotty et al. ("Crotty") teaching a cosmetic cream cleanser composition. A copy of U.S. Patent No. 6,696,068 is submitted herewith as Exhibit H. Crotty provides that the composition of the cream is from about 20,000 to about 500,000 cps. See Crotty, Abstract. Crotty further states the term "cream" requires a certain thickness and that consumers associate this thickness with creamy products. See Crotty, col. 1, lines 10-15. Appellant further notes Crotty was filed two months after Appellant's Application and is therefore certainly indicative of what was known and understood by one skilled in the art at the time the Application was filed. Appellant further submits, even the references relied upon by the Patent

Office, for example Lee, do not support the Patent Office's definition of a cream. Lee teaches expressly teaches that a viscosity in the range of 4000 to 8000 mPas (i.e., 4000 to 8000 cps) is a shower gel. See Lee, Abstract. Accordingly, the evidence submitted herewith shows that one of ordinary skill in the art would understand the term cream as having a viscosity outside of that which is taught by Imamura. Therefore, Imamura does not teach or suggest a base in the form of a cream as recited in Claim 5.

Thus, at least for the reasons discussed above, the Patent Office has failed to show that Imamura teaches or suggests at least the element of "a base in a form of a cream suitable for application to human skin" as recited in Claim 5. Accordingly, Appellant respectfully submits, the relied upon reference fails to teach or suggest every element of Claim 5. Since each and every element of Claim 5 is not taught or suggested by the reference of record, a *prima facie* case of obviousness has not been established.

For the foregoing reasons, the Patent Office has failed to establish that Imamura, teaches or suggests each of the elements of Claim 5 or its dependent claims. Accordingly, Appellant respectfully submits Claims 5 and 7 are separately patentable over Imamura and requests the rejection of Claims 5 and 7 under 35 U.S.C. §103 be overturned.

M. Rejection of Claim 21 Under 35 U.S.C. § 103 as Obvious over Imamura

In regard to Claim 21, this claim depends from independent Claim 1 and incorporates the limitations thereof. Thus, at least for the reasons mentioned in regard to Claim 1, the Patent Office has failed to establish, anticipation or a *prima facie* case of obviousness over Imamura for Claim 21.

In addition, Claim 21 is separately patentable over Imamura because it teaches the additional element of "wherein the composition may be left on the skin after application." The Patent Office alleges that for the same reasons previously set forth, this element does not patentably distinguish the claimed invention. See Final Action, page 10. Appellant respectfully traverses the Patent Office's rejection for at least the reasons previously discussed. Namely, the Patent Office has not established its initial burden of showing this feature is expressly, implicitly or inherently found within Imamura. Moreover, if the Patent Office believes that it is common knowledge that the composition taught by Imamura may be left on the skin after application, this fact must be supported by documentary evidence.

Thus, for these additional reasons, the Patent Office has failed to establish a *prima facie* case of obviousness for Claim 21 based on Imamura. Accordingly, Claim 21 is separately patentable over Imamura. Appellant respectfully requests the rejection of Claim 21 under 35 U.S.C. §103 be overturned.

N. Rejection of Claims 5 and 7 Under 35 U.S.C. § 103 as Obvious over Fox

The Patent Office rejects claims 5 and 7 under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Fox. In a previous response dated September 13, 2004, Appellant submitted an Affidavit under 37 CFR §1.131 to overcome the rejection of Fox. The Patent Office believes such Affidavit cannot be used where a U.S. patent claims the same invention, citing MPEP 715. With respect to obvious variations, the Patent Office relies upon paragraph 0013 of Fox to teach crystals preferably about 100 to 2000 microns and paragraph 0025 to teach that

other ratios of the claimed crystal to carrier ratio of 1 to 2 are permissible depending on sufficiency of abrasion and emulsion stability.

Thus, as previously discussed in regard to Messenger, the Patent Office has not shown how the rejected claims are an obvious variant of Fox for purposes of MPEP 715. The Patent Office is comparing the pending claims to examples in the specification of Fox, not the claims of Fox. Appellant believes, in this context, a 37 CFR 1.131 Affidavit is effective and respectfully requests that the Patent Office reconsider the Affidavit submitted.

For the foregoing reasons, the Patent Office has failed to establish that Fox teaches or suggests each of the elements of Claim 5 or its dependent claims. Accordingly, Appellant respectfully submits Claims 5 and 7 are separately patentable over Fox and requests the rejection of Claims 5 and 7 under 35 U.S.C. §102 or, in the alternative, 35 U.S.C. §103 be overturned.

O. Rejection of Claims 1, 2, 3, 21 and 22 Under 35 U.S.C. § 103 as Obvious over McAtee

In regard to Claim 1, McAtee fails to teach or suggest a composition comprising at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin." The Patent Office admits McAtee teaches a composition comprising a moisturizer in an amount lower than that recited in the claim, e.g. "about 20%." Nevertheless, the Patent Office alleges "about 23%" includes "about 20%."

McAtee teaches away from the conclusion reached by the Patent Office. McAtee teaches that the humectants and moisturizers can be present in the composition in a range "from about 0.1% to about 20%, more preferably from about 0.5% to about 15%, and most preferably from about 1% to about 10%." See McAtee, col. 13, lines 40-46. Thus, the teachings of McAtee suggest to one of ordinary skill in the art that the desirable range is certainly less than 20% and preferably between 1% and 10%. Accordingly, upon viewing McAtee the skilled artisan would not understand "from about 0.1% to about 20%" as recited in McAtee to include a higher range of "at least about 23%" as recited in Claim 1. Moreover, there is no teaching or suggestion within the references or otherwise provided by the Patent Office that including "about 23%" moisturizer in the composition of McAtee would still provide an acceptable composition. It is only upon viewing Appellant's disclosure that a range of "at least about 23%" is shown to be desirable. As the Patent Office is no doubt aware, such hindsight reconstruction may not be relied upon to modify a reference in an attempt to render claims obvious.

Thus, at least for the reasons discussed above, the Patent Office has failed to show that McAtee teaches or suggests at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin" as recited in Claim 1. Accordingly, Appellant respectfully submits, the relied upon reference fails to teach or suggest every element of Claim 1. Since each and every element of Claim 1 is not taught or suggested by the reference of record, a *prima facie* case of obviousness has not been established.

For the foregoing reasons, the Patent Office has failed to establish that McAtee, teaches or suggests each of the elements of Claim 1 or its dependent claims. Accordingly, Appellant respectfully submits Claims 1, 2, 3, 21 and 22 are separately patentable over McAtee and requests the rejection of Claims 1, 2, 3, 21 and 22 under 35 U.S.C. §103 be overturned.

P. Rejection of Claims 1, 2 and 22 Under 35 U.S.C. §102 as anticipated by or, in the alternative, Under 35 U.S.C. § 103 as Obvious over Wdowik

In regard to Claim 1, Wdowik fails to teach or suggest a composition comprising at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin." The Patent Office alleges Wdowik discloses a shaving cream containing potassium stearate, sodium stearate, lauric acid diethanolamide (1.60%), mineral oil (17%), stearic acid (0.13%), coconut fatty acid (0.68%), glycerine (3.2%), PVP (0.12%), perfume, water (57.58%), propellant and particulate additive (3%) about 75 microns in size. The Patent Office states in view of the above disclosure, Wdowik teaches a composition within the scope of Claim 1 or in the alternative renders Appellant's claims obvious because the Wdowik composition uses the same ingredients. Appellant respectfully disagrees for at least the following reasons.

The Patent Office has not pointed to a portion of Wdowik expressly teaching a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin. Presumably, the Patent Office is including water to meet this limitation. However, as previously discussed, water does not fall within the scope

of Appellant's claimed moisturizer and the Patent Office has provided no evidence suggesting it does.

Thus, at least for the reasons discussed above, the Patent Office has failed to show that Wdowik teaches or suggests at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the human skin" as recited in Claim 1. Accordingly, Appellant respectfully submits, the relied upon reference fails to teach or suggest every element of Claim 1. Since each and every element of Claim 1 is not taught or suggested by the reference of record, neither anticipation nor a *prima facie* case of obviousness has been established.

For the foregoing reasons, the Patent Office has failed to establish that Wdowik, teaches or suggests each of the elements of Claim 1 or its dependent claims. Accordingly, Appellant respectfully submits Claims 1, 2 and 22 are separately patentable over Wdowik and requests the rejection of Claims 1, 2 and 22 under 35 U.S.C. §102 or, in the alternative, 35 U.S.C. §103 be overturned.

Q. Rejection of Claim 21 Under 35 U.S.C. §102 as anticipated by or, in the alternative, Under 35 U.S.C. § 103 as Obvious over Wdowik

In regard to Claim 21, this claim depends from independent Claim 1 and incorporates the limitations thereof. Thus, at least for the reasons mentioned in regard to Claim 1, the Patent Office has failed to establish, anticipation or a *prima facie* case of obviousness over Wdowik for Claim 21.

In addition, Claim 21 is separately patentable over Wdowik because it teaches the additional element of "wherein the composition may be left on the skin

after application." Appellant presumes, the Patent Office alleges that for the same reasons previously set forth, this element does not patentably distinguish the claimed invention. Appellant respectfully traverses the Patent Office's rejection for at least the reasons previously discussed. Namely, the Patent Office has not established its initial burden of showing this feature is expressly, implicitly or inherently found within Wdowik. Wdowik teaches a shaving composition. Thus, the only feature of the composition that would necessarily be present based upon the teachings of Wdowik is that the composition is removed once it is applied to the skin, such as, with a razor. In addition, mineral oil is a principle component of the shaving composition. Moreover, if the Patent Office believes that it is common knowledge that the composition taught by Wdowik may be left on the skin after application, this fact must be supported by documentary evidence.

Thus, for these additional reasons, the Patent Office has failed to establish anticipation, or in the alternative, a *prima facie* case of obviousness for Claim 21 based on Wdowik. Accordingly, Claim 21 is separately patentable over Wdowik. Appellant respectfully requests the rejection of Claim 21 under 35 U.S.C. §102 or, in the alternative, 35 U.S.C. §103 be overturned.

R. Rejection of Claims 1, 2, 3, 22 and 23 Under 35 U.S.C. § 103 as Obvious over McLaughlin in view of Wdowik

In regard to Claim 1, the combination of McLaughlin and Wdowik fails to teach or suggest a composition comprising at least the element of "a base comprising at least about twenty three percent by weight a moisturizer suitable for application to the

human skin." The Patent Office alleges McLaughlin teaches a shaving composition containing water-soluble soap, a liquid oily material in the range from 12% to 25 %, with mineral oil being preferred. The Patent Office also notes various examples containing mixtures of mineral oil and glycerin.

McLaughlin, however, does not disclose a shaving composition comprising a plurality of abrasive particles having a particle size in the range of 50 microns to 556 microns. The Patent Office combines the teachings of McLaughlin with those of Wdowik. Wdowik states:

> One preferred exemplary shaving composition of the present invention is based on that described in U.S. Pat. No. 3,852,417 by McLaughlin, but includes added water insoluble organic additives as is follows:

Material	% by Weight
Potassium stearate	5.20
Sodium stearate	1.11
Lauric acid diethanolamide	1.60
Mineral oil (Saybolt viscosity of 75-100 seconds at 100° F.)	15.00
Stearic Acid	0.14
Cocunut fatty acid	0.68
Glycerine	3.20
Polyvinylpyrrolidone (Grade K-30)	0.12
Perfume	0.37
Water	57.58
Dichlorodifluoromethane	10.00
Particulate additive – Nylon fibers	5.00
Total	100.00%

Wdowik, column 4, line 64 thru column 5, line 17. Wdowik also provides:

Another exemplary composition is based on that described in McLaughlin, U.S. Pat. No. 3,852,417 and includes an abrasive and/or organic additives as follows:

Material	% by Weight
Potassium stearate	5.20
Sodium stearate	1.11
Lauric acid diethanolamide	1.60
Mineral oil (Saybolt viscosity of 75-100 seconds at 100° F.)	17.00
Stearic Acid	0.14
Cocunut fatty acid	0.68
Glycerine	3.20
Polyvinylpyrrolidone (Grade K-30)	0.12
Perfume	0.37
Water	57.58
Dichlorodifluoromethane	10.00
Particulate additive – Nylon fibers	3.00
Total	100.00%

Wdowik, Column 5, line 64 through Column 6, line 17.

The examples provided above in Wdowik show that the combination of Wdowik and McLaughlin does not yield the composition comprising a base "comprising at least about 23% by weight and moisturizer suitable for application to human skin" as specified in claim 1. In this case, we have an expert in the shaving composition field (Mark S. Wdowik) combining references and producing a result, shown in Wdowik, that does not fall within the language of claim 1 as noted above with respect to the discussion of Wdowik. Thus, claim 1 is not obvious over the cited references.

For the foregoing reasons, the Patent Office has failed to establish that McLaughlin in view of Wdowik, teaches or suggests each of the elements of Claim 1 or its dependent claims. Accordingly, Appellant respectfully submits Claims 1, 2, 3, 22 and 23 are separately patentable over McLaughlin in view of Wdowik and requests the rejection of Claims 1, 2, 3, 22 and 23 under 35 U.S.C. §102 or, in the alternative, 35 U.S.C. §103 be overturned.

S. Rejection of Claims 5 and 7 Under 35 U.S.C. § 103 as Obvious over McLaughlin in view of Wdowik

In regard to Claim 5, the combination of McLaughlin and Wdowik fails to teach or suggest at least the elements of a composition comprising "a base in a form of a cream suitable for application to human skin" and "a plurality of particles of corundum, wherein the plurality of particles of corundum are at least thirty five percent by weight of the composition." As previously set forth, the Patent Office recognizes McLaughlin

fails to teach or suggest the incorporation of particulate additives. Instead, the Patent Office relies upon Wdowik to teach this element.

With respect to particulate additives in shaving compositions, Wdowik provides:

> In most instances, from about 0.1% to about 20%, by weight will be adequate, while from about 1% to about 10% by weight is normally preferred. However, it is to be understood that in some instances an equivalent "effective amount" of insoluble particulate additives less than 0.1% and/or greater than 20%, by weight, and in thick pastes, solids, and gels even as high as 90% or greater may be used in the practice of the present invention.

Wdowik, column 3, lines 45-53

Accordingly, Wdowik does not cure the deficiencies of McLaughlin since Wdowik teaches that in thick pastes, solids and gels, "the effective amount" of insoluble particulate additives may be greater than 20 %. Wdowik identifies acceptable shave compositions as, "solid, gel, cream, liquid or aerosol." See Wdowik, col. 3, lines 3-33. Thus, Wdowik distinguishes creams from those compositions that might have effective amounts of particulates greater than 20%.

Thus, at least for the reasons discussed above, the Patent Office has failed to show that either McLaughlin or Wdowik, alone or in combination, teach or suggest a composition comprising both "a base in a form of a cream suitable for application to human skin" and "a plurality of particles of corundum, wherein the plurality of particles of corundum are at least thirty five percent by weight of the composition" as recited in Claim 5. Accordingly, Appellant respectfully submits, the relied upon references fails to teach or suggest every element of Claim 5. Since each and every

element of Claim 5 is not taught or suggested by the reference of record, a *prima facie* case of obviousness has not been established.

For the foregoing reasons, the Patent Office has failed to establish that McLaughlin in view of Wdowik, teaches or suggests each of the elements of Claim 5 or its dependent claims. Accordingly, Appellant respectfully submits Claims 5 and 7 are separately patentable over McLaughlin in view of Wdowik and requests the rejection of Claims 5 and 7 under 35 U.S.C. §103 be overturned.

T. Rejection of Claim 21 Under 35 U.S.C. § 103 as Obvious over McLaughlin in view of Wdowik

In regard to Claim 21, this claim depends from independent Claim 1 and incorporates the limitations thereof. Thus, at least for the reasons mentioned in regard to Claim 1, the Patent Office has failed to establish, anticipation or a *prima facie* case of obviousness over McLaughlin in view of Wdowik for Claim 21.

In addition, Claim 21 is separately patentable over McLaughlin in view of Wdowik because it teaches the additional element of "wherein the composition may be left on the skin after application. Both McLaughlin and Wdowik describe shaving compositions where it is not intended that the compositions be retained on the skin after application. Thus, at least for the reasons discussed above, the Patent Office has failed to show that the reference teaches or suggests at least the elements of "wherein the composition may be left on the skin after application" as recited in Claim 21.

Thus, for these additional reasons, the Patent Office has failed to establish a *prima facie* case of obviousness for Claim 21 based on McLaughlin in view of Wdowik.

Accordingly, Claim 21 is separately patentable over McLaughlin in view of Wdowik. Appellant respectfully requests the rejection of Claim 21 under 35 U.S.C. §103 be overturned.

Accordingly, it is submitted that the rejections of claims 1-3, 5, 7 and 21-23 based on 35 U.S.C. §§ 102 and/or 103 be overturned.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN

Dated: February 17, 2006

By: _____
William Thomas Babbitt, Reg. No. 39,591

12400 Wilshire Boulevard
Seventh Floor
Los Angeles, California 90025
(310) 207-3800

CERTIFICATE OF MAILING:

I hereby certify that this correspondence is being deposited as First Class Mail, with the United States Postal Service in an envelope with sufficient postage addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 17, 2006.

Jean Svoboda

VIII. CLAIMS APPENDIX

The claims involved in this Appeal are as follows:

1. (Previously Presented) A composition comprising:

a base comprising at least about twenty three percent by weight a moisturizer suitable for application to human skin; and

a plurality of abrasive particles having a particle size in the range of 50 microns to 556 microns.

2. (Previously Presented) The composition of claim 1, wherein the moisturizer comprises at least one of a liquid, a gel, and an emollient.

3. (Previously Presented) The composition of claim 1, wherein the abrasive particles comprise at least one of corundum and magnesium oxide.

5. (Previously Presented) A composition comprising:

a base in the form of a cream suitable for application to human skin; and

a plurality of particles of corundum suspended in the base having an average particle size from 34 to 124 microns, and

wherein the plurality of particles of corundum are at least thirty five percent by weight of the composition.

7. (Original) The composition of claim 5, further comprising at least one of a vitamin, a mineral, an antioxidant, a cleanser, and an emulsifier.

21. (Previously Presented) The composition of claim 1, wherein the composition may be left on the skin after application.

22. (Previously Presented) The composition of claim 1, wherein the plurality of abrasive particles are suspended in the moisturizer.

23. (Previously Presented) The composition of claim 1, wherein the plurality of abrasive particles are at least thirty five percent by weight of the composition.

IX. EVIDENCE APPENDIX

A. Exhibit A

Appellant respectfully submits herewith a document titled "Mohseni Consultants" illustrating a microderm abrasion cream base of the instant application as Exhibit A. Appellant respectfully submits, this evidence was submitted along with Appellant's Declaration Pursuant to 37 CFR §1.131 submitted and entered by the Examiner with the Response to Office Action mailed September 13, 2004.

B. Exhibit B

Appellant respectfully submits herewith a document entitled "Mohseni Consultants" illustrating a microderm abrasion cream of the instant application as Exhibit B. Appellant respectfully submits, this evidence was submitted along with Appellant's Declaration Pursuant to 37 CFR §1.131 submitted and entered by the Examiner with the Response to Office Action mailed September 13, 2004.

C. Exhibit C

Appellant respectfully submits herewith a Declaration Pursuant to 37 CFR §1.131 as Exhibit C. Appellant respectfully submits, this evidence was submitted and entered by the Examiner with the Response to Office Action mailed September 13, 2004.

D. Exhibit D

Appellant respectfully submits herewith an excerpt from *The American Heritage Dictionary of the English Language*, Fourth Edition (2000) found at www.dictionary.com as Exhibit D. Appellant respectfully requests the evidence be entered for consideration on appeal.

E. **Exhibit E**

Appellant respectfully submits herewith a document titled "Topical Drug Bioequivalence: FDA Revised Strategy to be Presented to Committee; Reporting CMC Changes Also on Agenda." Appellant respectfully submits, this evidence was submitted and entered by the Examiner with the Response to Office Action mailed November 17, 2003 and the Response to Office Action mailed September 13, 2004.

F. **Exhibit F**

Appellant respectfully submits herewith a definition of cream provided by a cosmetic and ingredients glossary at www.corycosmetics/cosmetic_ingredients_glossary.htm. Appellant respectfully submits, this evidence was referenced in the Response to Office Action mailed September 13, 2004 and thus entered by the Examiner.

G. **Exhibit G**

Appellant respectfully submits herewith an article provided by a liquid control website at www.liquidcontrol.com. Appellant respectfully submits, this evidence was submitted and entered by the Examiner with the Response to Office Action mailed September 13, 2004.

H. **Exhibit H**

Appellant respectfully submits herewith a copy of U.S. Patent No. 6,696,068 issued to Crotty et. al. as Exhibit H. Appellant respectfully requests the evidence be entered for consideration on appeal.

F.1

MOHSENI CONSULTANTS
PRODUCT:Microderm Abrasion Cream base
FORMULA : #980910
DATE: 9/15/1998

NO	%	DESCRIPTION	GRAM	POUND	INTL
1	63.432	DI WATER			
2	0.30	50% PANTHENOL			
3	2.00	PROPYLENE GLYCOL			
4	0.20	METHYLPARABEN			
5	5.00	DEHYHAG WAX			
6	8.00	LIPONATE CG			
7	6.00	SAFFLOWER OIL			
8	7.00	OCTYL PALMITATE			
9	0.10	PROPYLPARABEN			
10	0.05	ASCORBYL PALMITATE			
11	.050	LECITHIN			
12	3.50	STEARIC ACID			
13	0.20	CETYL ALCOHOL			
14	2.00	WHEAT GERM OIL			
15	0.10	VITAMIN E ACETATE			
16	0.01	VITAMIN A			
17	.050	CAROT EXTRACT			
18	.010	WHEAT GERM EXTRACT			
19	0.500	PHENPXYETHANOL			
20	0.380	AMP 95			
21	0.800	LUMINESSENSE236-270			
22	0.001	2%BETA CAROTENE			
23	0.144	FDC YELLOW 5 1%			
24	0.173	FD yellow 6 1%			

MOHSENI CONSULTANTS

PRODUCT:Microdermabrasion Cream

FORMULA : # 980911

DATE : 9/15/1998

NO	%	DESCRIPTION	GRAM	POUND	INTL
1	50.0	MICRDERMABRASION CREAM BASE FORMULA # 980910			
2	50.0	WHITE ALUMINUM OXIDE 120			
3					
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Our Ref. No.: 5309P001X

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	
Dean L. Rhoades	Examiner: Frank I. Choi
Application No.: 09/802,425	
Filed: March 9, 2001	Art Unit: 1616
For: COMPOSITION, APPARATUS AND METHOD FOR SKIN REJUVENATION	

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION PURSUANT TO 37 C.F.R. § 1.131

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Dean L. Rhoades, hereby declare that:

1. I am a citizen of the United States of America.

2. I currently reside at 2075 N. Beverly Drive, Beverly Hills, California 90210.

3. I am the inventor of the above-identified patent application.

7. I have reviewed U.S. Patent No. 6,290,976 issued to Messenger (the "Messenger" patent) which was filed on April 6, 2000 and Patent Application Publication No. US 2002/0090385 filed by Fox et al (the "Fox" publication) which was based on a provisional application 60/239,059 filed on October 5, 2000. The Examiner has cited the Messenger patent and Fox publication against the claims of the above-identified application.

8. The invention disclosed and claimed in the above-identified patent application was reduced to practice in the United States of America at least as early as September 15, 1998, as evidenced by the attached documents which are printouts of two formulations (Exhibit A and B). Exhibit A is a formulation of a creme base having moisturizer ingredients that are twenty percent by weight of the base. Exhibit B is a formulation of a composition with the creme base of Exhibit A and aluminum oxide with a particle size of 120 microns. These documents demonstrate the reduction to practice of the invention prior to the earliest priority date of Messenger and Fox.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Respectfully submitted,

Dated: 9-7-04

Dean L. Rhoades

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2 entries found for *moisture*.

mois·ture Pronunciation Key (mois'chər)
n.

1. Diffuse wetness that can be felt as vapor in the atmosphere or condensed liquid on the surfaces of objects; dampness.
2. The state or quality of being damp.

[Middle English, from Old French, from `moiste`, *moist*. See **moist**.]

[Download Now or Buy the Book]
Source: *The American Heritage® Dictionary of the English Language, Fourth Edition*
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moisture

n : wetness caused by water; "drops of wet gleamed on the window" [syn: wet]

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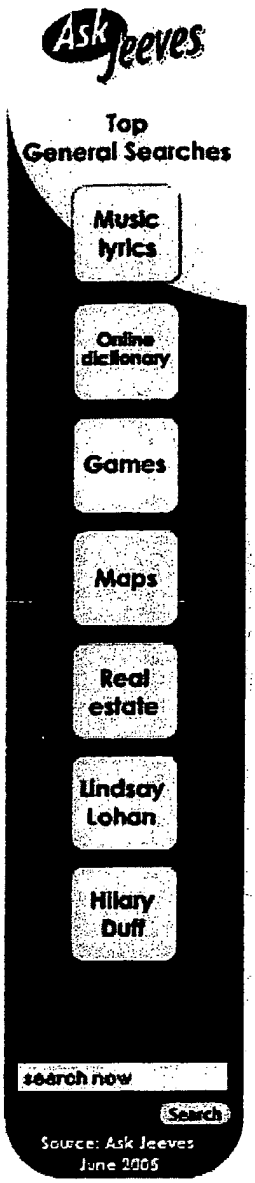
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Topical Drug Bioequivalence: FDA Revised Strategy To Be Presented To Committee; Reporting CMC Changes Also On Agenda

FDA will present its proposed "future direction" for ensuring therapeutic equivalence of topical drug products to the Pharmaceutical Science Advisory Committee during a March 12 meeting.

In response to concerns about use of dermatopharmacokinetics, or skin stripping, to determine bioequivalence that were raised by committee members at a Nov. 29, 2001 meeting, FDA withdrew its draft guidance on DPK. The agency said it now plans to take a "fresh look" at the best methods to determine bioequivalence of generic topical dermatologic products.

The committee will be asked to comment of FDA's "current proposed direction" and whether other alternatives should be considered. The agency noted, however, that this meeting is primarily to make the committee aware of the issue and that in depth discussions will take place at future meetings.

FDA will also present its proposed system for classifying topical drug products. The committee will be asked for its input on the proposed nomenclature.

For example, the committee will be asked whether it is "reasonable" to distinguish lotion from cream on the basis of viscosity. Under the agency's proposed definitions, a lotion contains >50% volatiles (as measured by loss on drying) and has a viscosity of <30,000 cps, while a cream has a viscosity >30,000 cps.

FDA would like input on whether there is any value to including attributes such as greasy, non-greasy or cooling in the definitions. Other questions include whether it is worthwhile to draw a distinction between hydrophilic and lipophilic creams and whether the presence of an emulsifier in a formulation should preclude a dosage form from being classified as a gel.

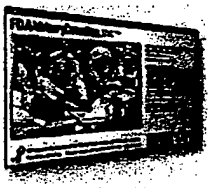
The agency will also update the committee on the use of comparability protocols for post-approval changes in manufacturing processes. FDA issued a draft guidance on the subject in February.

On March 13 the committee will hear an overview on the Office of Pharmaceutical Science's research capabilities, discuss a proposal for parametric tolerance interval testing of aerosol products, and hear an overview on the evaluation of bioavailability and bioequivalence of endogenous drug products.

To watch a live or archived webcast of this meeting, click the button below. To arrange for live videoconferencing or to order videotapes and CDs. email webcasthelp@elsevier.com or call 800-332-1370 ext. 7210.

Posted: Monday, March 10, 2003

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MEETING INFORMATION

This meeting will be held March 12, 2003 at the Advisory Committee Conference Room, Center for Drug Evaluation & Research, 5630 Fishers Lane in Rockville, Md. beginning at 8:30 a.m.

Agenda
Briefing Information
Committee Information
Questions

RELATED STORIES

- Topical Dermatological Drugs Bioequivalence Methods To Be Topic Of March 12 Meeting [Posted: 1/13/03]
- Topical Drug Nomenclature Being Redefined By FDA [Posted: 3/12/03]

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soaps. Go to the Fruits & Vegetables Dictionary and look up Corn.

Corn Oil
Corn oil is used as a skin soother and softener (emollient). It is rich in linoleic acid, one of the three essential fatty acids.

Corn Silk
Corn silk is a soothing diuretic, that acts as a urinary demulcent (soothing, coating herb that can protect irritated or inflamed tissue).

Corn Starch
Used to absorb water and soothe the skin.

Cortisol
Hydrocortisone. The main glucocortisteroid secreted by the cortex of the adrenal gland.

Cortisone
A glucocortisteroid. Cortisone relieves inflammation, pain, and swelling.

Cosmeceutical
An unrecognized term by the Food, Drug, and Cosmetic Act. In the cosmetic industry the word refers to a cosmetic product with drug-like benefits. Note: The FDA does not approve cosmetics prior to sale.

Cosmetics
Products used for the purposes of cleansing, beautifying, promoting attractiveness or alternating ones appearance.

Cream
A preparation for the skin used to impart moisture. A cream is usually thicker and more emollient (soother and softener) than a lotion.

Cream Rinse
A mixture of wax, thickeners, and a group of chemicals used to coat the hair shaft and detangle the hair. Generally applied after shampooing.

Cucumber
Known for its astringent and soothing properties it is an ingredient often found in facial creams, lotions, and cleansers. It can also be used as an anti-inflammatory agent (slices placed over puffy eyes can reduce swelling). Go to the Fruits & Vegetables Dictionary and look up Cucumber.

Cucumber Extract
An extract with anti-inflammatory actions and skin tightening properties.

Cucumber juice
A juice with moisture binding, soothing and tightening properties.

Curbicia Extract
A plant extract which helps regulate the skin's production of sebum. Used in hair treatments.

Metering Pump Technology
Fixed- & Variable-Ratio Designs
Mixer Technology
Dispense Valve Technology
Material Feed Systems

P-200 Throughput Calculator
C-500 Throughput Calculator
Viscosity
Fillers
Vacuum
Application Data & Calculations

Abbreviations & Symbols
Applications Glossaries

VISCOSITY

Viscosity is the measurement of a fluid's internal resistance to flow. This is typically designated in units of centipoise or poise but can be expressed in other acceptable measurements as well. Some conversion factors are as follows:

100 Centipoise = 1 Poise
1 Centipoise = 1 mPa s (Millipascal Second)
1 Poise = 0.1 Pa s (Pascal Second)
Centipoise = Centistoke x Density

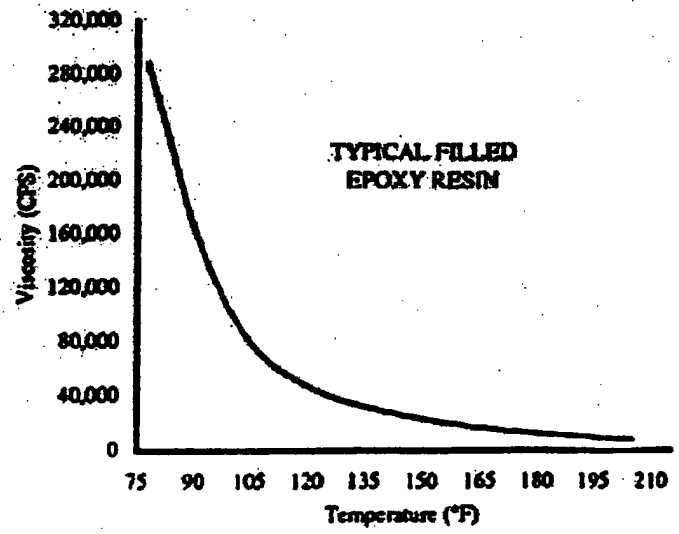
Newtonian materials are referred to as true liquids since their viscosity or consistency is not affected by shear such as agitation or pumping at a constant temperature. Water and oils are examples of Newtonian liquids.

Thixotropic materials reduce their viscosity as agitation or pressure is increased at a constant temperature. Ketchup and mayonnaise are examples of thixotropic materials. They appear thick or viscous but actually pump quite easily.

Paste viscosity is a vague term the viscosity of many materials but needs further definition to design a machine. Some paste viscosity materials will seek their own level or flow slowly and the shorter the time it takes, the easier they are to pump. Others do not seek their own level or flow at all and require pressure to move them from the supply container (cartridges, pails or drums) to the metering pump. These materials require special consideration regarding their feeding into metering pumps to assure the metering pump does not cavitate or to prevent air from being introduced into the material.

One way to differentiate between easy and difficult to flow pastes is to obtain Brookfield viscosities using the same spindle at two different rotational speeds, usually a tenfold difference (e.g. 1 RPM and 10 RPM). This will provide a "thixotropic index" for the particular material. The higher the difference in viscosity at the two speeds, the more thixotropic the material is and easier to pump.

To reduce the viscosity of paste materials to allow easier pumping, heat is often applied. The following graph illustrates how a typical filled epoxy resin reduces in viscosity as it is heated.



Solid materials at room temperature that are designed to be melted to allow pumping require heating above their melt point before they become a liquid. Maintaining heat on this material throughout the metering system (feed tank, pump, material supply hose, mixer, etc.) is normally critical to preventing this material from resolidifying somewhere in the system. A heated cabinet that encapsulates all wetted components of the machine is typically employed instead of just heat blanketing the various components.

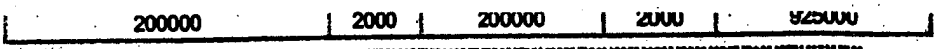
| Approximate Viscosities of Common Materials (At Room Temperature-70|F) | |
|---|---|
| **Material** | **Viscosity in Centipoise** |
| Water | 1 cps |
| Milk | 3 cps |
| SAE 10 Motor Oil | 85-140 cps |
| SAE 20 Motor Oil | 140-420 cps |
| SAE 30 Motor Oil | 420-650 cps |
| SAE 40 Motor Oil | 650-900 cps |
| Castrol Oil | 1,000 cps |
| Karo Syrup | 5,000 cps |
| Honey | 10,000 cps |
| Chocolate | 25,000 cps |
| Ketchup | 50,000 cps |
| Mustard | 70,000 cps |
| Sour Cream | 100,000 cps |
| Peanut Butter | 250,000 cps |

Viscosity Conversion Chart

The following viscosities are based on materials with a specific gravity of one.

Centipoise (CPS) or Millipascal (mPas)	Poise (P)	Centistokes (CKS)	Stokes (S)	Saybolt Universal (SSU)
1	0.01	1	0.01	31
2	0.02	2	0.02	34
4	0.04	4	0.04	38
7	0.07	7	0.07	47
10	0.1	10	0.1	60
15	0.15	15	0.15	80
20	0.2	20	0.2	100
25	0.24	25	0.24	130
30	0.3	30	0.3	160
40	0.4	40	0.4	210
50	0.5	50	0.5	260
60	0.6	60	0.6	320
70	0.7	70	0.7	370
80	0.8	80	0.8	430
90	0.9	90	0.9	480
100	1	100	1	530
120	1.2	120	1.2	580
140	1.4	140	1.4	690
160	1.6	160	1.6	790
180	1.8	180	1.8	900
200	2	200	2	1000
220	2.2	220	2.2	1100
240	2.4	240	2.4	1200
260	2.6	260	2.6	1280
280	2.8	280	2.8	1380
300	3	300	3	1475
320	3.2	320	3.2	1530
340	3.4	340	3.4	1630

400	4	400	4	1950
420	4.2	420	4.2	2050
440	4.4	440	4.4	2160
460	4.6	460	4.6	2270
480	4.8	480	4.8	2380
500	5	500	5	2480
550	5.5	550	5.5	2660
600	6	600	6	2900
700	7	700	7	3380
800	8	800	8	3880
900	9	900	9	4300
1000	10	1000	10	4600
1100	11	1100	11	5200
1200	12	1200	12	5620
1300	13	1300	13	6100
1400	14	1400	14	6480
1500	15	1500	15	7000
1600	16	1600	16	7500
1700	17	1700	17	8000
1800	18	1800	18	8500
1900	19	1900	19	9000
2000	20	2000	20	9400
2100	21	2100	21	9850
2200	22	2200	22	10300
2300	23	2300	23	10750
2400	24	2400	24	11200
2500	25	2500	25	11600
3000	30	3000	30	14500
3500	35	3500	35	16500
4000	40	4000	40	18500
4500	45	4500	45	21000
5000	50	5000	50	23500
5500	55	5500	55	26000
6000	60	6000	60	28000
6500	65	6500	65	30000
7000	70	7000	70	32500
7500	75	7500	75	35000
8000	80	8000	80	37000
8500	85	8500	85	39500
9000	90	9000	90	41080
9500	95	9500	95	43000
15000	150	15000	150	69400
20000	200	20000	200	92500
30000	300	30000	300	138500
40000	400	40000	400	185000
50000	500	50000	500	231000
60000	600	60000	600	277500
70000	700	70000	700	323500
80000	800	80000	800	370000
90000	900	90000	900	415500
100000	1000	100000	1000	462000
125000	1250	125000	1250	578000



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